reaction site are non-toxic, non-irritant, non-carcinogenic, and otherwise do not produce any undesired or inconvenient physical reactions in the user.

The following description highlights several preferred embodiments of the present invention. The present invention is not limited to these illustrative examples. While the following description highlights the use of test strips for oral use, it should be understood that the other configurations are within the scope of the present invention. The detailed description is provided in the following sections: I) Assay Tests; II) Delivery Systems; and III) Analytes.

## I. Assay Tests

### A. Description

The assay test is preferably small in size so that it can be easily carried. For example, in some embodiments, the assay test forms a 'strip' and is rectangular, flat, and thin, such that multiple assay test strips can be stored in a delivery system that is convenient to carry. An example of a test strip in one embodiment of the present invention is shown in Figure 18.

In preferred embodiments, the components of the assay test of the present invention are contained within a single device so that it is easy to use. The assay tests comprises three main components: a solid support, a collection site and a reaction means. In some embodiments, the assay tests comprise a desiccant material.

#### 1. Solid Support

The assay test comprises a solid support providing both a handle or free end to hold the test with as well as providing a substrate for other compositions (*e.g.*, collection site). In embodiments where the assay test comprises a test strip, the solid support is typically a thin paper, filter, or plastic material wherein one end of the strip provides the free end to hold, while the other end of the strip contains the collection site and reaction means. In some embodiments, the solid support comprises a desiccant material.

### 2. Collection Site

The assay test comprises a collection site for collecting a sample. In some embodiments of the assay test, the collection site comprises an absorbent material that can absorb a sample (*e.g.*, a fluid such as saliva) from an individual. In some embodiments, the sample flows from the absorbent material to a reaction means (*e.g.*, by diffusion), while in other embodiments the collection site is physically introduced near a reaction means such that the sample is introduced to the reaction means. In yet other embodiment, the reaction means and collection site are in contact with one another or are integrated. Several assay test formats that allow the introduction of the sample from an absorbent material to a reaction means are described below. In other embodiments of the present invention, a sample is directly introduced into a reaction means without an absorbent material (*e.g.*, by introduction of fluid into a collection site comprising a well or chamber).

In some embodiments, the assay test is provided with a stimulator, configured to stimulate saliva production in the mouth. These embodiments are employed, where it is desired or necessary to have large volumes of saliva or where newly produced saliva provides a more accurate correlation to blood concentrations of analyte (e.g., for glucose detection). Any physical (e.g., a physical protrusion the enters the mouth and provokes salivation), psychological (e.g., images or scents the stimulate salivation), or chemical (e.g., saliva stimulation tablets that do not interfere with the detection chemistry; flavors) methods for stimulating saliva production are contemplated.

### 3. Reaction Means

The assay test further comprises a reaction means for detecting the presence of analyte in a sample. A wide variety of reaction means are compatible with the present invention. Acceptable reaction means are those that can be incorporated into the assay tests of the present invention and that can maintain a detectable signal in the presence of analyte. Reaction components that find use in the detection of particular analytes are described in Section III, below. In some embodiments, the reaction means

comprises an enzyme that reacts with the analyte, directly or indirectly, to generate a reaction product that is directly or indirectly detected. For example, enzymes that react with analytes and produces an oxidized or reduced reaction product find use in the present invention. In some embodiments, the oxidized or reduced product is used is a reaction with a chromogen to produce a visibly detectable color. In some embodiments, a series of reactions are used to amplify the signal. For example, reaction products of a first reaction are each used to generate multiple reaction products in a second reaction. The reaction products of the second reaction are then used in subsequent reactions, eventually leading to the generation of detectable response.

In some embodiments, the reaction means provides a qualitative measurement of analyte concentration. In some embodiments, the presence of a detectable signal indicates the presence of an analyte, without indicating a specific amount of the analyte. In other embodiments, the detectable signal appears when a particular threshold analyte concentration is present. While this indicates that the concentration of analyte is above a certain concentration, it does not provide a quantitative measure of actual analyte concentration. In some embodiments, the detectable signal (e.g., color) increases with increasing analyte concentration. An estimate of analyte concentration is made by comparing the level of detectable signal to a chart or table representing ranges of analyte concentration that correspond to an approximate level of detectable signal. In some embodiments, the detectable signal is measured to determine a quantitative amount analyte in the sample. In some embodiments, one or more control test assays are used to assist in quantitative determination (e.g., a second test assay is used on a sample with known analyte concentration).

In other embodiments, of the present invention, a biosensor is used. A wide variety of biosensors find use in the reaction means of the present invention, including, but not limited to the biosensors described in U.S. Patents 5,571,395, 5,792,621, 5,500,351, and 6,183,772, incorporated herein by reference in their entireties. In some embodiments, the biosensor employs an antibody. In some embodiments of the present invention, the reaction means provide a colorimetric response that intensifies